REMARKS

Currently, claims 1-6, 8-23 and 29-34 are pending in the application, claims 7 and 24-28 being withdrawn as a result of a restriction requirement and election of species.

Claim 1 is amended to correct an antecedent basis detail; claim 2 is amended for clarity with basis for the amendment at page 4, lines 16-18. Claim 29 is amended to further require that the raised apex is located between ends of the stent component (rather than at the ends). Basis is provided in figures 1A, 2, 3 and 5A-5C which clearly indicate this location between the ends of the stent. Claim 34 is also amended herein; basis for the amendment is at page 4, lines 8-21.

I. APPLICANTS' INVENTION

The present invention relates to removable device such as a stent-graft, intended for applications where it may be desirable to remove the device at some time following implantation. The stent-graft includes a helically-wound stent component provided with a covering of graft material. It is removable by gripping an end of the helically-wound stent component with a retrieval device and applying tension to the stent component in the direction in which it is intended to be withdrawn from the site of implantation. The use of such a retrieval device allows the stent-graft to be removed remotely, such as via a catheter inserted into the body at a different location from the implantation site. The design of the stent-graft is such that the stent component is extended axially while the adjacent portion of the graft separates between windings of the stent component. The axial extension of the stent component, with portions of the graft still joined to the stent component, allows the device to be "unraveled" (or "unwound") and removed through a catheter of diameter adequately small to be inserted into the body cavity that contained the stent-graft. It is removed atraumatically, without incurring significant trauma to the body conduit in which it had been deployed.

II. OBJECTION TO SPECIFICATION

The length and phraseology of the Abstract are objected to. An amended Abstract is submitted herewith that addresses the objections.

III. OBJECTION TO CLAIM 20 UNDER 37 CFR 1.75(c).

Claim 20 is objected to as being the same as claim 18, with respect to all claimed limitations. Applicants respectfully disagree. Claim 18 depends from claim 17 (which depends from claim 1), claim 17 specifying that the graft material comprises a tape having a length that is adapted for splitting along its length. Claim 20 depends from claim 19 which in turn depends from claim 1; claim 19 adds limitations to the effect of requiring that the tape and stent component are

helically oriented at pitch angles that are substantially the same. Thus while the language of claims 18 and 20 is the same, the different dependencies result in different limitations. Claim 18 requires that the tape is longitudinally splittable while claim 20 requires that the tape and stent components are helically oriented at substantially the same pitch angles. As such, the limitations of these claims clearly differ.

IV. REJECTION OF CLAIM 34 UNDER 35 USC 102(b) AS ANTICIPATED BY SCHWARTZ et al., US PATENT 5,799,384.

Schwartz et al. teach the construction of a stent-graft made from a length of serpentine wire having a length of a "flexible film" material joined to the length of the wire, with the wire more or less centered between the edges of the strip of flexible film. The wire and attached strip of flexible film are helically wound (by wrapping around a mandrel that is subsequently removed) to create the tubular stent-graft. The adjacent edges of adjacent helical windings of the flexible film are specified as not being bonded or otherwise sealed together.

The Examiner is of the opinion that, because the adjacent edges of the graft material of the Schwartz et al. device are not attached to each other, that the graft material of that device is capable of being split (defined by the Examiner as "separated").

Applicants respectfully disagree with the Examiner's position. First, Schwartz et al. do not teach or suggest removability of their device following implantation, so such separation of their helically wrapped graft material would not happen without the intention of removing the stent-graft by unwinding. Second, if the helical windings are never joined to form a substantially continuous luminal surface and thus remain separate and discrete "layers," they cannot be said to be "splittable" as presently claimed. This "splittable" character of the present invention is described at page 4, lines 16-20 and (for example) by Figure 2. Schwartz et al. does not teach or suggest splittability as taught by the present application. The "separated" character commented on by the Examiner is clearly not the same as the integral or continuous graft material of the present invention that is "splittable" as taught by the present specification.

Regardless, in order to clarify the differences between the present invention and Schwartz et al., claim 34 is amended herein to specify that the graft material covers spaces between adjacent elements of the stent component in a substantially continuous fashion. This is also clearly different from and not anticipated by the graft covering taught by Schwartz et al.

V. REJECTION OF CLAIMS 1-6, 8-10, 12-15, 17-20, 22 AND 33 UNDER 37 CFR 103(a) AS UNPATENTABLE OVER SCHWARTZ et al., US PATENT 5,799,384 IN VIEW OF BOSLEY, JR., US PATENT 5,514,176.

Schwartz et al. is described above. Bosley, Jr. teaches the construction of a removable stent-graft in the form of a helically wound non-serpentine coil (which may be made of a variety of materials including wire) provided with a covering (preferably an outer covering) of a material such as silicone that secures adjacent coil loops together. The adjacent coil loops are specified to be in abutting relationship (see, for example, the first paragraph of the Summary of the Invention at col. 2, lines 40-53 and all figures; also please note the second sentence of the Abstract and the first sentence of the Detailed Description at col. 4, lines 10-11).

The Examiner states that Schwartz et al. discloses an endoprosthesis with all the elements of claims 1 and 33, but adds that Schwartz et al. is silent as to removability of the endoprosthesis by cohesive disassembly.

Applicants agree as to the silence of Schwartz et al. regarding removability. However, Schwartz et al. do not disclose the claimed elements of the present invention. Both claims 1 and 33 require that the graft material forms a continuous luminal surface. Schwartz et al., by specifying that their endoprosthesis is formed as described above without joining or adhering of the adjacent edges of the strip of flexible film attached to the helically wound serpentine wire, clearly teach away from the continuous luminal surface of the present invention. This continuous character of the graft material of the present invention is defined at page 4, lines 14-23. Lines 18-20 of this text state that "the graft material is substantially integral prior to removal and does not include gaps between adjacent windings of the stent component (as shown by, for example, US Patent 5,799,384) prior to removal." This continuous character is entirely different from the discontinuous character of the graft material described by Schwartz et al. Indeed, Schwartz et al., in requiring that the graft material is discontinuous between adjacent helical windings, teach away from the use of a graft material that forms a continuous luminal surface.

Further, due to the required abutment of the adjacent coils of Bosley, Jr., that reference cannot be combined with Schwartz et al. in that Schwartz et al. specify a space between adjacent windings of their serpentine wire that are spanned by the strip of flexible film attached to each winding. Bosley, Jr. clearly teaches away from any space between adjacent stent windings. Likewise, Bosley Jr. teaches that the silicone coating over the abutted coils is continuous, contrary to the discrete strip of film used by Schwartz et al. that results in a discontinuous lumen. The teachings of these two references are clearly at odds with each other in these two fundamentally different regards, with the result that either of these references cannot be combined with the other without changing the other to an extent entirely contrary to the requirements of the other. The

person of ordinary skill would not consider combining these contrary references without benefit in hindsight of the teachings of the present invention.

Still further in this same regard, Bosley, Jr. teaches that his device is "substantially imperforate" between adjacent coils (col. 4, lines 14-15, among various other locations throughout the specification). The Schwartz et al. device, with adjacent edges of the film-covered helical windings specified to not be joined together, is entirely perforate between the windings. Again, the person of skill would not consider such a contrary combination.

Regarding claim 2, the Examiner states that this claim only includes functional language and fails to further structurally limit the invention. He adds that the graft material of Schwartz et al. is capable of tearing, particularly at the point of the slit or v-shaped cut shown in Figure 3. Claim 2 is amended herein to clarify that the tearing of the graft material occurs between adjacent elements of the stent component during disassembly. It is clear that the flexible film of Schwartz et al. does not tear between adjacent elements of the stent component; indeed, as noted above, Schwartz et al. teach away from joining or adhering together the strip of flexible film attached to the helically wound wire. Even if Schwartz were to teach removability by applying tension to the wire end to cause unwinding, the flexible film would not tear because it is discontinuous to begin with. Schwartz et al. does not teach or suggest the tearing specified in claim 2, particularly as that claim is amended herein.

Regarding the other dependent claims, they are patentable for all of the reasons that claims 1 and 33 are patentable. Several things are worth noting as they relate to the Examiner's comments directed to these dependent claims. The comments directed to claims 3-6, 8 and 9 rely on the combination of the two cited references, which are not combinable as described above. Regarding claim 10 and any impermeability of the graft material of Schwartz (col. 4, lines 8-10), the graft material of Schwartz is hardly impermeable with the adjacent edges of each helical winding of the flexible film not being sealed together in any way. With respect to the foreshortening limitations of claims 12 and 13, a measurement of the length of the Schwartz prosthesis shown in Figures 7 and 8 (before and after balloon expansion of the prosthesis) does not indicate any foreshortening; any appearance of such is optically the result of the change in transverse diametrical dimension. The specification is silent as to foreshortening.

Claim 14 relates to the ability of the graft material to be cohesively disassembled during graft removal. This claim also depends from claim 1 and as such also requires that the graft material forms a continuous luminal surface. Again, there is nothing in Schwartz et al. (including the referenced Figure 3) that suggests making the endoprosthesis with a continuous luminal surface. As to claim 15 (also dependent to claim 1), while Bosley, Jr. (col. 7, lines 21-23) suggests

that his device may be removed with minimal trauma, it still requires the abutted coils that are contrary to claim 1 of the present invention.

Claims 17-20 and 22 (each of which is ultimately dependent on claim 1) relate to the use of a tape material as the graft material. The tape of the graft material of the present invention has adjacent edges that when helically wound are joined together to produce a continuous luminal surface that is splittable as shown by Figure 2. The tape itself is splittable parallel to its length (page 11, lines 15-18). Again, this is not the same as non-joined adjacent tape edges that that are simply separated.

The present invention is not obvious over the combination of Schwartz et al. and Bosley, Jr.; these references have opposing requirements that prevent their combination; even if they were considered to be combinable they offer no reason to combine without benefit of hindsight based on the present specification.

VI. REJECTION OF CLAIMS 11, 16 AND 21 UNDER 37 CFR 103(a) AS UNPATENTABLE OVER SCHWARTZ et al., US PATENT 5,799,384 AND BOSLEY, JR., US PATENT 5,514,176 AS APPLIED TO CLAIMS 1 AND 20 ABOVE, AND FURTHER IN VIEW OF SMITH, US PATENT 6,364,904.

Smith teaches the construction of a stent-graft from materials that include ePTFE, which is known to be permeable. Claims 11, 16 and 21 relate to permeability of the graft material and the use of ePTFE as the graft material. As described above, the present claims are patentable over Schwartz et al. and Bosley, Jr. for the same reasons described above for claims 1, 33 and 34.

VII. REJECTION OF CLAIM 23 UNDER 37 CFR 103(a) AS UNPATENTABLE OVER SCHWARTZ et al., US PATENT 5,799,384 AND BOSLEY, JR., US PATENT 5,514,176 AS APPLIED TO CLAIMS 22 ABOVE, AND FURTHER IN VIEW OF BIGUS et al., US PATENT 6,629,992.

The Examiner describes that Schwartz et al. describes means for splitting being a cut and that Bigus et al. teach an endoprosthesis wherein a sheath is provided with perforations as an alternative to a cut to provide the sheath with a weakened area at a desired location. He concludes that it would have been obvious to look to the teachings of Bigus et al. in order to provide perforations as a means of providing a weakened area that would split.

First, the cuts of Schwartz et al. are not intended to provide for splitting of the graft material but rather to provide flexibility to the serpentine wire from which the stent is wound and strain relief to the graft material in order to accommodate the change in diameter of the stent-graft during balloon expansion. These cuts are provided during manufacture of the stent-graft. There is no

suggestion that they are present to allow for splitting or tearing of the graft material during removal of the graft by unwinding or unraveling. Indeed, as noted above, Schwartz et al. do not suggest graft removal by any means including unwinding.

Likewise, the perforations taught by Bigus et al. are longitudinally oriented and intended to allow for splitting of a sheath that constrains a self-expanding endoprosthesis prior to deployment to a larger diameter. The splitting of the sheath to initiate deployment releases the constrained stent allows it to self-expand.

It is clear that the sheath is not intended as a functional part of the endoprosthesis, but rather only as a component provided for stent delivery and deployment. As such, this teaching is not suggestive of a splittable graft material that is part of the stent-graft. The entirely different orientation of the splittable material is also not suggestive of the helical orientation of the perforations necessary to allow for removal of the present stent-graft. These differences are such that the person of skill would be extremely unlikely to look to Bigus et al. for teachings related to the construction of a stent-graft including a graft material that forms a continuous luminal surface that may be cohesively dissembled to allow its removal, as by tearing or splitting of the graft material between adjacent elements of the stent component.

VIII. REJECTION OF CLAIMS 29 AND 31 UNDER 37 CFR 103(a) AS UNPATENTABLE OVER SCHWARTZ et al., US PATENT 5,799,384 IN VIEW OF CULLY et al., WO00/42949.

Claim 29 is amended herein to further require that the raised apex, covered by the graft material, is located between the ends of the stent.

Schwartz et al., as described above, teach the construction of a stent-graft from a length of serpentine wire to which is affixed a strip of flexible film. The serpentine wire with attached strip of film is subsequently wrapped into a helical form wherein adjacent edges of the film of adjacent helical windings are not sealed together, resulting in a discontinuous luminal surface. Cully et al. teach a stent-graft with a continuous luminal surface that includes a length of helically wound serpentine wire as the stent component. Some apices located between the ends of the stent-graft are raised to serve as in vivo tissue anchors. The raised apices of Culley et al. are not covered by the graft material; rather they remain open and allow tissue to grow into the open loop formed by the raised wire apex.

The Examiner concludes that, given the raised apex teaching of Cully et al., it would be obvious to raise at least one apex of the helically wound serpentine wire of Schultz et al. to form an anchor provided with covering of the attached graft material.

There are several difficulties with this conclusion. First, Cully et al. teach the construction of a biliary stent-graft intended to be impermeable at relatively high pressures (see Culley et al. at

page 2, line 33 to page 3, line 23). Schwartz et al., in teaching away from the sealing of adjacent windings, cannot serve in any pressure-resistant application that would allow leakage through the wall of the device as would happen between adjacent windings of the graft of Schwartz et al. with its discontinuous luminal surface. Thus anyone considering the teaching of Schwartz et al. for a stent-graft would not be considering the biliary graft teachings of Cully et al.

Further, both references teach the construction of a tubular device wherein the luminal and exterior surfaces of the graft material form relatively smooth luminal and exterior surfaces (continuous or discontinuous) with, in the case of the Culley et al. reference, the occasional raised wire apex extending above the graft material. There is no suggestion in either reference to provide the covering over a raised apex that would disrupt the tubular shape of the graft material. It is simply counter-intuitive to do this and is not taught or suggested in either reference.

IX. REJECTION OF CLAIMS 30 AND 32 UNDER 37 CFR 103(a) AS UNPATENTABLE OVER SCHWARTZ et al., US PATENT 5,799,384 AND CULLY et al., WO00/42949 AS APPLIED TO CLAIMS 29 AND 31 ABOVE, AND FURTHER IN VIEW OF BOSLEY, JR., US PATENT 5,514,176.

These claims depend respectively from claims 29 and 31 as argued above. Their language is the same, each requiring that the endoprosthesis is adapted to be cohesively disassembled to allow for removal. Thus the arguments presented above pertaining to claims 29 and 31 apply here. Likewise, the previous arguments directed to cohesive removal apply here as well. Finally, Culley et al. do not teach or suggest removability. Ultimately, these references in combination do not teach removability of a stent graft with spaces between adjacent elements of the generally helically wound wire covered by a graft material that forms a continuous luminal surface and is adapted for cohesive disassembly to allow for removal of the endoprosthesis from a patient.

CONCLUSION

The applicants believe that their claims as amended are in good and proper form and are patentable over the cited art. As such, the applicants respectfully request reconsideration, allowance of the claims and passage of the case to issuance. If there remain any issues that might benefit from further discussion, the Examiner is requested to telephone the undersigned practitioner; likewise, the Applicants request an interview if such issues may remain.

Respectfully Submitted,

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